

510(k) Summary

Date Prepared: November 27, 2013
Company: Surgical Specialties Corporation
100 Dennis Dr.
Reading, PA 19606
Contact: Kirsten Stowell
Regulatory Affairs Manager
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NOV 29 2013

Device trade name: TranQuill barbed device, comprised of Polydioxanone

Device Common Name: Polydioxanone Absorbable Surgical Suture

Device classification: Absorbable polydioxanone surgical suture
Product code, NEW
21 CFR 878.4840
Class II

Legally marketed device to which the device is substantially equivalent:

K051609:	Quill Synthetic Absorbable Barbed Suture
K080680	Quill™ Self-Retaining System (SRS) comprised of PDO
K080985	Quill™ Self-Retaining System (SRS) comprised of PDO

Description of the device: The TranQuill barbed device is a sterile, synthetic absorbable device that is intended for use in the approximation of soft tissue. It is comprised of polyester [poly (p-dioxanone)], dyed with D&C Violet No. 2. The device is designed with small bi-directional barbs along the long axis of the suture monofilament. It is available in diameter Size 0 through 2-0 in various lengths affixed to various needle types.

Indications for Use: The TranQuill barbed device comprised of dyed PDO is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.

**Substantial
Equivalence:**

The TranQuill barbed device comprised of polydioxanone has the same design and materials as the Quill™ Synthetic Absorbable Barbed Suture predicate device, including the same intended use and technological characteristics as the predicate device. The only difference between the proposed and predicate device is the decrease in spacing between barbs.

Performance tests:

Non-clinical laboratory performance testing was conducted to confirm that the TranQuill barbed device comprised of polydioxanone, conforms to the USP monograph for absorbable sutures for tensile strength (as applicable) and *in vitro* barb holding strength. This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Surgical Sutures, Issued June 3, 2003. Additional performance testing was conducted in order to demonstrate substantial equivalence to the predicate device including *in vitro* post-hydrolysis tensile testing.

The results of this testing demonstrates that the TranQuill barbed device comprised of polydioxanone, is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Surgical Specialties Corporation
Ms. Kirsten Stowell
Regulatory Affairs Manager
100 Dennis Drive
Reading, Pennsylvania 19606

January 23, 2014

Re: K133420

Trade/Device Name: TranQuill Barbed Device
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: November 6, 2013
Received: November 8, 2013

Dear Ms. Stowell:

This letter corrects our substantially equivalent letter of November 29, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joshua C. Nipper -S

FOR Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K133420

Device Name
TranQuill Barbed Device, comprised of Polydioxanone

Indications for Use (Describe)

The TranQuill barbed device comprised of polydioxanone, is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

David Krause -S